



Docket No. 04-100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: King et al)
Serial No.: 10/810,829) Art Unit: 1651
Filed: 03/29/2004) Examiner:
For: ELECTRODES COATED WITH TREATING AGENT) Fernandez, Susan
AND USES THEREOF)

DECLARATION UNDER RULE 1.131

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Sir:

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1. Introduction

In the Official Action dated 04-19-05 for the above-identified case, the Examiner rejected a number of the Applicant's original claims under 35 USC § 102 and 35 USC § 103 with reliance upon Wang (6,514,762).

This DECLARATION UNDER RULE 1.131 is filed concurrently with an AMENDMENT for the above-identified case. In the AMENDMENT, independent claim 25 is amended, and the amended form of claim 25 is referred to as "currently amended independent claim 25".

2. Rejections of Applicant's claimed invention relying upon Wang (6,514,762)

In the Official Action dated 04-19-05 for the above-identified case, the Examiner rejected 25, 29, 31-34, 37, 40-43, 46-47, and 49-50 under 35 USC § 102 as being anticipated by Wang (6,514,762).

In addition, the Examiner rejected originally filed claims 25-27, 29-34, 37, 40-43, and 49-50 under 35 USC § 103 as being unpatentable over Wang (6,514,762) in view of Gross et al (5,356,632).

In addition, the Examiner rejected originally filed claims 25-34, 37, 40-43, and 46-50 under 35 USC § 103 as being unpatentable over Wang (6,514,762) in view of Gross et al (5,356,632) and further in view of Hofmann (6,009,347).

In addition, the Examiner rejected originally filed claims 25, 29, 31-35, 37, 40-43, and 46-47, and 49-50 under 35 USC § 103

as being unpatentable over Wang (6,514,762) in view of Vadgama et al (WO 92/05434).

In addition, the Examiner rejected originally filed claims 25, 29, 31-35, 37, 40-43, 46-47, and 49-50 under 35 USC § 103 as being unpatentable over Wang (6,514,762) in view of Hoffmann et al (5,902,329).

In addition, the Examiner rejected originally filed claims 25, 29, 31-34, 37-43, 46-47, and 49-50 under 35 USC § 103 as being unpatentable over Wang (6,514,762) in view of Zewert et al (5,749,847) and/or Widera et al (Journal of Immunology).

In addition, the Examiner rejected originally filed claims 25, 29, 31-34, 37, 40-47, and 49-50 under 35 USC § 103 as being unpatentable over Wang (6,514,762) in view of Lerner (WO 97/18855).

3. Independent claims in Wang (6,514,762)

Here are independent claims 1, 11, and 21 in Wang (6,514,762):

1. A method for controlled release of nucleic acids, comprising the steps of:
 - adsorbing nucleic acids to be released on at least one first electrode;
 - providing a second electrode;
 - immersing the first electrode and second electrode in an aqueous media in which the nucleic acids are to be released; and providing a negative electrical charge to the first electrode relative to the second electrode for a determined period of time sufficient to release at least a portion of the adsorbed nucleic acids over the period of time;
 - whereby the release of the nucleic acids is proportional to the relative electrical charge difference and period of persistence of the charge difference.

11. A method for controlled release of nucleic acids, comprising the steps of:

 adsorbing nucleic acids to be released on at least one first electrode;

 providing a second electrode;

 immersing the first electrode and second electrode in an aqueous media in which the nucleic acids are to be released;

 selecting a negative electrical charge to be applied to the first electrode relative to the second electrode, the negative electrical charge being sufficient to remove a portion, but less than all, of the adsorbed nucleic acids over a selected period of time;

 selecting a period of time for the negative electrical charge to be applied to the first electrode relative to the second electrode; and

 providing the negative electrical charge to the first electrode relative to the second electrode for the selected period of time, the negative electrical charge and period of time being sufficient to release a portion of the adsorbed nucleic acids.

21. A method for controlled release of nucleic acids, comprising the steps of:

 adsorbing one or more nucleic acids to be released, the nucleic acids comprising a structure between about a 25-mer oligonucleotide and a 350 base pair double-stranded nucleic acid, on at least one first electrode, the first electrode comprising a member selected from the group consisting of glassy carbon electrodes, carbon paste electrodes, metallic electrodes and metal-coated crystal wafer electrodes;

 providing a second electrode;

 immersing the first electrode and second electrode in a physiologically compatible aqueous media in which the nucleic acids are to be released;

 selecting a negative electrical charge to be applied to the first electrode relative to the second electrode, the negative electrical charge being sufficient to remove a portion, but less than all, of the adsorbed nucleic acids over a selected period of time;

 selecting a period of time for the negative electrical charge to be applied to the first electrode relative to the second electrode; and

 providing the negative electrical charge to the first electrode relative to the second electrode for the selected period of time, the negative electrical charge and period of time being sufficient to release a portion of the adsorbed nucleic acids.

4. Applicant's originally filed independent claim 25 and Applicant's currently amended independent claim 25

Here is the Applicant's originally filed independent claim 25:

Claim 25. (Original) An electrode which includes a coating having at least one static layer of electrode releasable molecules to be delivered into biological cells.

Here is the Applicant's currently amended independent claim 25:

Claim 25. (Currently amended) An electrode for penetration into tissues which includes a coating having at least one static layer of releasable molecules to be delivered into biological cells in the penetrated tissues by an applied electric field.

Clearly, the Applicant's invention (as either originally claimed or as amended) is not claimed in Wang (6,514,762).

5. Comparison of the effective filing date of Wang (6,514,762) and the completion of the Applicant's invention in the United States

Wang (6,514,762) has an effective filing date of April 23, 1999, which was a filing date of a U. S. provisional patent application.

In sharp contrast, the Applicant's invention has a United States Provisional Patent Application Serial No. 60/117,755, with a filing date of January 28, 1999.

Clearly, the filing date of January 28, 1999 of the Applicant's invention is before the filing date of April 23, 1999 of Wang (6,514,762). In this respect, the Applicant swears behind Wang (6,514,762).

More specifically, in the Official Action of 04-19-05, the Examiner cited Wang (6,514,762) for its following disclosures:

- a. a method of DNA vaccine delivery (on pages 5, 15, 17, 19, 20, and 22 of the Official Action); and
- b. an electrode with a solid coating (on pages 5, 15, 18, 19, 21, and 22 of the Official Action).

Now, turning to the Applicant's invention as disclosed in the United States Provisional Patent Application, Serial No. 60/117,755, with a filing date of January 28, 1999, here are important disclosures therein that predate the filing date of Wang (6,514,762).

First, on page 6, in the section entitled "Delivery using electrical charge", there is a disclosure of binding macromolecules to the external surface of the electrode.

Second, on page 7, under the title "DNA as an example", DNA, which is a solid material, is coated on an electrode.

Third, on page 8, in the paragraph entitled "Delivery to skin", there is a disclosure of delivering a DNA vaccine into biological cells using electrodes that penetrate the skin.

In view of the above, it is clear that Wang (6,514,762) should not be applied as a reference for any purpose against either the Applicant's originally claimed invention or the Applicant's currently claimed invention.

6. The showing of facts to establish the filing of a U. S. provisional patent application by the Applicant prior to the effective date of Wang (6,514,762)

Attached hereto is a Certified and True Copy of United States Provisional Patent Application Serial No. 60/117,755, with a filing date of January 28, 1999. The Certified and True Copy was obtained from the U. S. Patent and Trademark Office.

7. Conclusion

In view of the fact that the disclosures in the Applicant's United States Provisional Patent Application Serial No. 60/117,755, with a filing date of January 28, 1999, predate the disclosures in Wang (6,514,762) that were cited by the Examiner, the Wang (6,514,762) patent should be removed as a reference for the rejection of the Applicant's currently claimed invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may

jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

August 18, 2005

Date

Marvin S. Townsend

Marvin S. Townsend
Registration Number 27,959
Attorney for Applicant

Marvin S. Townsend
Patent Attorney
8 Grovepoint Court
Rockville, MD 20854
(Voice and Fax) 301-279-0660
E-mail: MTowsend@aol.com

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